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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/508,806	09/21/2004	Armin Bernhard	BAW-0010	3944

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EXAMINER	
FLORY, CHRISTOPHER A	
ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
12/11/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/508,806	BERNHARD, ARMIN	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7,8 and 10-12* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7,8 and 10-12* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 October 2008 has been entered.

Response to Arguments

2. Applicant's arguments, see paragraph 2 of page 4, filed 22 September 2008, with respect to the §101 rejection of claim 1 have been fully considered and are persuasive. The §101 rejection of claim 1 has been withdrawn.

3. Applicant's arguments, see paragraphs 3-5 of page 4, filed 22 September 2008, with respect to the rejection of claim 1 under 35 U.S.C. §112, first paragraph have been fully considered and are persuasive. The §112 rejection of claim 1 has been withdrawn.

4. Applicant's remaining arguments filed 22 September 2008 have been fully considered but they are not persuasive. Claims 1-4, 8, 10 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Ball'376 or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ball'376 in view of Kroll'662 or in view of Brillhart'637. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ball'376 in view of Baumann'115; or alternatively over Ball'376 in view of either Kroll'662 or Brillhart'637,

f.i.v. Baumann'115. Claims 7 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Ball'376 in view of Lesinski et al. (US Patent 5,531,787) and in view of Leysieffer et al. (US Patent 6,398,717), or alternatively over Ball'376 in view of either Kroll'662 or Brillhart'637, f.i.v. Leysieffer et al. Additionally, claims 1-4, 8, 10 and 11 are newly rejected under 102(e) as being anticipated by Puria et al. (US 6,629,922) previously made of record.

Regarding Applicant's arguments that Ball'376 does not teach interrupting the ossicular chain such that the incus and stapes, or any replacement thereof, are permanently disconnected and that the incus move independently from the stapes or any replacement thereof, it is noted that the limitation is presented in the alternative such that only one condition need be met (i.e., either the stapes, or a replacement thereof, *but not both*). As the original rejection stands for the reasons made of record and represented again herein, one of the alternatives is considered to be met and therefore the claims are not distinguishable over the prior art. Additionally, it is noted that several of the embodiments of Ball'376 shown in the figures to do not require the sound transducer be reconnected to the incus, and thus also read on the limitation that the "replacement thereof" is permanently disconnected. The presentation of the claim limitation in the alternative also renders the Applicant's arguments regarding "any replacement thereof" (see pages 6 and 7) moot.

In response to Applicant's argument that Ball'376 does not teach a sound receiver but rather a transducer that processes vibrations, it is noted that sound is vibrational energy, particularly as it applies to sounds entering the ear, such that a

vibrational transducer as disclosed in Ball'376 can be considered a sound receiver, as it is receiving the vibrational representation of sound as it enters the ear, or at the very least is capable of such function due to its identical structure.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Kroll'662 and Brillhart'637 properly motivate not only permanent disconnection of the ossicular chain but a means by which such a disconnection is operative. Additionally, the showing above that Ball'376 does in fact disclose the supposedly absent claim limitations renders the Applicant's arguments (see pages 9-10) moot.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 8, 10 and 11 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Puria et al. (US 6,629,922, hereinafter Puria'922).

Particular emphasis is placed on Figures 1A, 2E, 2F, 4C, 4D and their related paragraphs.

Claim Rejections - 35 USC § 102/103

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-4, 8, 10 and 11 stand rejected under 35 U.S.C. 102(b) as anticipated by Ball et al. (US Patent 5,624,376, hereinafter referred to as Ball'376) or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ball'376 in view of Kroll et al. (US 6,540,662, hereinafter Kroll'662) or in view of Brillhart et al. (US 6,585,637, hereinafter Brillhart'637).

Regarding claim 1, Ball'376 discloses a sound receiver from an implantable hearing aid (TITLE; ABSTRACT) comprising an implantable electromechanic transducer which converts the force resulting of an accelerated mass into an electric signal (Figs. 3-5, transducer 100; ABSTRACT); the sound receiver providing a mounting mechanism on at least one of the ossicles in the ossicle chain (abstract; Figs. 8-10; Fig. 5, titanium prongs 52).

Further regarding claim 1, specifically the clause that the sound receiver be rigidly fixed to the malleus or incus, whereby incus and stapes, or any replacement thereof, are disconnected so that the incus can move independently from the stapes or any replacement thereof, the embodiments of Ball'376 shown in Figure 9 can be reasonably interpreted as anticipating this claim limitation. Regarding Figure 9, a partial prosthetic embodiment, Ball'376 shows the sound transducer 100 connected to the incus MM by way of a prosthetic member 38c. Since member 38c and sound transducer 100 form a singular prosthetic device, sound transducer 100 can reasonably be interpreted as being rigidly connected to the incus since subcomponent 38a is rigidly fixed to both the transducer and the incus. Although it is not a direct connection, it is nonetheless a rigid connection. In this embodiment, the stapes is completely removed from the system. It is very clear that in this case, the incus and stapes are permanently disconnected from one another and are now moving independently. Contrary to Applicant's arguments, removal of the stapes does not in any way suggest that Ball'376 "fails to teach a stapes at all," since the stapes must be taught in order to teach that the stapes is removed. Additionally, removal of the stapes does not prevent Ball'376 to read on the currently amended claims, which simply state that "the incus and stapes are permanently disconnected," which in no way provides necessity of the stapes to remain within the body.

Alternatively, in the same field of endeavor, Kroll'662 teaches that a removal of the stapes (i.e. a permanent disconnect of the incus from the stapes) acts to disarticulate the ossicular chain to prevent feedback and permit the malleus and incus

to remain in place, which further aids in preventing damage from acoustical trauma by allowing the natural musculoskeletal defense mechanisms to protect against it (column 5, lines 40-50; column 6, line 51 through column 7, line 7). Similarly, in the same field of endeavor, Brillhart'637 teaches that disarticulation of the ossicular chain creates a feedback barrier to prevent retrograde transmission of sound energy through the external auditory canal and tympanic membrane to the microphone, and further defines an embodiment (Fig. 4) in which the incus and stapes are disarticulated and fixed within the middle ear but not removed with a separation of 2-3 millimeters in order to prevent a rejoining of the two bones (column 5, lines 37-43; column 6, line 62 through column 7, line 21). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system and method of Ball'376 with a permanent disconnection of the incus and stapes as taught by either Kroll'662 or Brillhart'637 to provide the Ball'376 system and method with the same advantages of preventing retrograde feedback of sound energy to the microphone and prevent acoustical trauma by allowing the natural musculoskeletal defense mechanisms to protect against such trauma.

It is further noted that each of the applied references is considered to positively read on the newly amended limitation of feedlines connecting the sound receiver to a signal processing unit. Namely Ball'376 shows leads 24 in Figures 4, 10, 14, 18, 19a, 23 and 24, each of which is considered to be a feedline. Kroll'662 shows feedlines in Figure 3, element 110; Figure 5, element 160; and Figure 6, element 126. Brillhart'637 shows feedlines clearly in Figures 3 and 7.

Regarding claim 2, Ball'376 discloses the floating mass transducer comprising a piezoelectric transducer (ABSTRACT; column 3, lines 24-45).

Regarding claims 3 and 11, Ball'376 discloses the transducer and hermetic housing to be made of biologically compatible material (column 7, lines 30-35; column 8, lines 10-21 and 50-55; column 10, lines 15-25).

Regarding claim 4, Ball'376 discloses a metallic conductive housing (column 8, lines 35-55; column 9, lines 30-35).

Regarding claim 8, Ball'376 discloses a vibratory structure placed inside the housing (ABSTRACT).

Regarding claim 10, the embodiments shown in Figs. 8-10, 14, 18 and 19a of Ball'376 can be considered cochlear implants, because they have the function of enhancing the throughput to the inner ear through the oval window, thus enhancing or augmenting the natural function of the cochlea.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ball'376 in view of Baumann et al. (US Patent Publication 2002/0138115); or alternatively over Ball'376 in view of either Kroll'662 or Brillhart'637, f.i.v. Baumann et al.

Regarding claim 5, Ball'376, or Ball'376 v. Kroll'662 or v. Brillhart'637, discloses the invention substantially as claimed, but does not expressly disclose that the sound receiver further comprise an A/D-converter and an impedance transformer inside the housing. In the same field of endeavor, Baumann et al. teaches an implantable hearing aid with both an A/D converter (Fig. 2, A/D converters 30 and 31; paragraphs [37]-[40]) and an impedance transformer (paragraph [66]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Ball'376 with the A/D converter and impedance transformer of Baumann et al. to provide the same advantages of more efficiently processing data and amplifying the input voltage.

11. Claims 7 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Ball'376 in view of Lesinski et al. (US Patent 5,531,787) and in view of Leysieffer et al. (US Patent 6,398,717), or alternatively over Ball'376 in view of either Kroll'662 or Brillhart'637, f.i.v. Leysieffer et al.

Regarding claims 7 and 12, Ball'376, or Ball'376 v. Kroll'662 or v. Brillhart'637, discloses the invention substantially as claimed, but does not expressly state that the sound receiver have an entire mass of less than 50 and 30 milligrams respectively. In the same field of endeavor, Lesinski et al. teaches a microsensor with a mass of less than 30 milligrams (column 9, line 50 through column 10, line 7; claim 7). Likewise, in the same field of endeavor, Leysieffer et al. teaches an implant with a total mass of 25 mg on average in order to reduce the forces of inertia upon acceleration by external effects such as impact and vibration and thereby minimize loss of signal in the ossicle chain (column 11, lines 55-65). Therefore, it would have been obvious to one of

ordinary skill in the art at the time of the invention to modify the system of Ball'376 with a mass of less than 30 milligrams as taught in both Lesinski et al. and Leysieffer et al. in order to provide the Ball'376 system with the same advantages of reducing inertial forces and minimizing signal loss in the middle ear (motivation to combine provided by Leysieffer et al., column 11, lines 55-65). In the alternative, it would have been obvious to one having skill in the art at the time of the invention was made to make a sound receiver with a relatively small mass, such as less than 30 milligrams, since it has been held to be within the general skill of a worker in the art to select known materials and components on the basis of their suitability for the intended use, such as light weight, as a matter of obvious design choice. Since the Ball'376 device discloses each and every one of the structural components of the claimed invention, it follows that one of ordinary skill in the art could select light-weight or miniaturized components and materials to construct a transducer of less than 30 milligrams.

12. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Puria'922 in view of Baumann et al. (US Patent Publication 2002/0138115).

Regarding claim 5, Ball'376 Puria'922 discloses the invention substantially as claimed, but does not expressly disclose that the sound receiver further comprise an A/D-converter and an impedance transformer inside the housing. In the same field of endeavor, Baumann et al. teaches an implantable hearing aid with both an A/D converter (Fig. 2, A/D converters 30 and 31; paragraphs [37]-[40]) and an impedance transformer (paragraph [66]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Puria'922 with the A/D converter

and impedance transformer of Baumann et al. to provide the same advantages of more efficiently processing data and amplifying the input voltage.

13. Claims 7 and 12 rejected under 35 U.S.C. 103(a) as being unpatentable over Puria'922in view of Lesinski et al. (US Patent 5,531,787) and in view of Leysieffer et al. (US Patent 6,398,717.

Regarding claims 7 and 12, Puria'922 discloses the invention substantially as claimed, but does not expressly state that the sound receiver have an entire mass of less than 50 and 30 milligrams respectively. In the same field of endeavor, Lesinski et al. teaches a microsensor with a mass of less than 30 milligrams (column 9, line 50 through column 10, line 7; claim 7). Likewise, in the same field of endeavor, Leysieffer et al. teaches an implant with a total mass of 25 mg on average in order to reduce the forces of inertia upon acceleration by external effects such as impact and vibration and thereby minimize loss of signal in the ossicle chain (column 11, lines 55-65). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system of Puria'922 with a mass of less than 30 milligrams as taught in both Lesinski et al. and Leysieffer et al. in order to provide the Puria'922 system with the same advantages of reducing inertial forces and minimizing signal loss in the middle ear (motivation to combine provided by Leysieffer et al., column 11, lines 55-65). In the alternative, it would have been obvious to one having skill in the art at the time of the invention was made to make a sound receiver with a relatively small mass, such as less than 30 milligrams, since it has been held to be within the general skill of a worker in the art to select known materials and components on the basis of their suitability for the

intended use, such as light weight, as a matter of obvious design choice. Since the Puria'922 device discloses each and every one of the structural components of the claimed invention, it follows that one of ordinary skill in the art could select light-weight or miniaturized components and materials to construct a transducer of less than 30 milligrams.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Christopher A. Flory/

10 December 2008

/George Manuel/
Primary Examiner